IN THE CLAIMS

This listing of the claims replaces all prior versions of the claims in the application.

1-11. (canceled)

12. (currently amended): A method of treating a subject for a breast cancer characterized by overexpression of the HER2 receptor protein, said method comprising concurrent therapy with an anti-HER2 antibody ~~or fragment thereof~~ that has anti-tumor activity and an interleukin-2 (IL-2) polypeptide comprising the sequence of SEQ ID NO:1 or biologically active variant thereof, wherein said anti-HER2 antibody ~~or fragment thereof binds the same epitope as~~ comprises a complementarity determining region (CDR) of an anti-HER2 antibody selected from the group consisting of 4D5 (ATCC Number CRL-10463) and 520C9 (ATCC Number HB-8696), wherein said anti-HER2 antibody binds to the extracellular domain of the HER2 receptor protein, wherein said concurrent therapy comprises administering to said subject at least one therapeutically effective dose of said IL-2 or variant thereof in combination with a dosing regimen for said anti-HER2 antibody ~~or fragment thereof~~, wherein said dosing regimen for said anti-HER2 antibody ~~or fragment thereof~~ comprises administering to said subject at least one therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.5 MIU/m^2 to about 4.0 MIU/m^2; wherein said variant of said IL-2 has anti-tumor activity and ~~comprises an amino acid sequence having~~ at least 90% sequence identity to SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4, and wherein said anti-HER2 antibody ~~or fragment thereof~~ binds to the extracellular domain of the HER2 receptor protein.

13. (currently amended): The method of claim 12, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is in the range from about 2.0 mg/kg to

about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.6 MIU/m^2 to about 3.0 MIU/m^2.

14. (currently amended): The method of claim 13, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.8 MIU/m^2 to about 1.5 MIU/m^2.

15. (currently amended): The method of claim 14, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is about 4.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is about 1.0 MIU/m^2.

16. (currently amended): A method of treating a subject for a breast cancer characterized by overexpression of the HER2 receptor protein, said method comprising concurrent therapy with an anti-HER2 antibody ~~or fragment thereof~~ that has anti-tumor activity and an interleukin-2 (IL-2) polypeptide comprising the sequence of SEQ ID NO:1 or biologically active variant thereof, wherein said anti-HER2 antibody ~~or fragment thereof binds the same epitope as~~ comprises a complementarity determining region (CDR) of an anti-HER2 antibody selected from the group consisting of 4D5 (ATCC Number CRL-10463) and 520C9 (ATCC Number HB-8696), wherein said anti-HER2 antibody binds to the extracellular domain of the HER2 receptor protein, wherein said concurrent therapy comprises a first administration of a therapeutically effective dose of said IL-2 or variant thereof on day 1 of a treatment period followed by a first administration of a therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ within 6 days of said first administration of said therapeutically effective dose of said IL-2 or variant thereof to said subject, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.5 MIU/m^2 to about 4.0 MIU/m^2; wherein said variant of said IL-2 has anti-tumor activity and ~~comprises an amino acid sequence having~~ at least 90% sequence identity to SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length

penalty of 12, and a gap penalty of 4, and wherein said anti-HER2 antibody ~~or fragment thereof~~ binds to the extracellular domain of the HER2 receptor protein.

17. (currently amended): A method of treating a subject for a breast cancer characterized by overexpression of the HER2 receptor protein, said method comprising concurrent therapy with an anti-HER2 antibody ~~or fragment thereof~~ that has anti-tumor activity and an interleukin-2 (IL-2) polypeptide comprising the sequence of SEQ ID NO:1 or biologically active variant thereof, wherein said anti-HER2 antibody ~~or fragment thereof binds the same epitope as~~ comprises a complementarity determining region (CDR) of an anti-HER2 antibody selected from the group consisting of 4D5 (ATCC Number CRL-10463) and 520C9 (ATCC Number HB-8696), wherein said anti-HER2 antibody binds to the extracellular domain of the HER2 receptor protein, wherein said concurrent therapy comprises multiple dosing of a therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ and a therapeutically effective dose of said IL-2 or variant thereof, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.5 MIU/m^2 to about 4.0 MIU/m^2; wherein said variant of said IL-2 has anti-tumor activity and ~~comprises an amino acid sequence having~~ at least 90% sequence identity to SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120 weight residue table, a gap length penalty of 12, and a gap penalty of 4, and wherein said anti-HER2 antibody ~~or fragment thereof~~ binds to the extracellular domain of the HER2 receptor protein.

18. (currently amended): The method of claim 17, wherein said multiple dosing comprises administering to said subject said therapeutically effective dose of said IL-2 or variant thereof and said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ during an introductory cycle, wherein said introductory cycle comprises daily administration of said therapeutically effective dose of said IL-2 or variant thereof on day 1 of said introductory cycle through day 20 of said introductory cycle, and a single administration of said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ on day 7 of said introductory cycle.

19. (currently amended): The method of claim 18, further comprising administering said therapeutically effective dose of said IL-2 or variant thereof and said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ during at least one subsequent cycle, wherein said subsequent cycle comprises daily administration of said therapeutically effective dose of said IL-2 or variant thereof on day 1 of said subsequent cycle through day 14 of said subsequent cycle, and administration of said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ on day 1 of said subsequent cycle.

20. (previously presented): The method of claim 18, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of said IL-2 or variant thereof, wherein said intermediate dose is about 12.0 MIU/m^2.

21. (previously presented): The method of claim 19, further comprising intermediate-dose IL-2 pulsing on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of said IL-2 or variant thereof, wherein said intermediate dose is about 12.0 MIU/m^2.

22. (previously presented): The method of claim 12, wherein said IL-2 or variant thereof is administered subcutaneously.

23. (previously presented): The method of claim 12, wherein said anti-HER2 antibody comprises at least one human constant region.

24. (canceled)

25. (currently amended): The method of claim 12, wherein said anti-HER2 antibody is a humanized or chimeric form of a murine antibody selected from the group consisting of 4D5 (ATCC Number CRL-10463) and 520C9 (ATCC Number HB-8696).

26. (previously presented): The method of claim 12, wherein said therapeutically effective dose of said IL-2 or variant thereof is administered as a pharmaceutical composition selected from the group consisting of a monomeric IL-2 pharmaceutical composition, a multimeric pharmaceutical IL-2 composition, a lyophilized IL-2 pharmaceutical composition, and a spray-dried IL-2 pharmaceutical composition.

27. (previously presented): The method of claim 26, wherein said IL-2 or variant thereof is recombinantly produced.

28. (previously presented): The method of claim 27, wherein said variant is des-alanyl-1, serine-125 human interleukin-2.

29. (currently amended): The method of claim 28, wherein said anti-HER2 antibody ~~or fragment thereof~~ comprises at least one human constant region.

30. (currently amended): The method of claim 28, wherein said anti-HER2 antibody is ~~selected from the group consisting of~~ a humanized anti-HER2 antibody, a chimeric anti-HER2 antibody, or a human anti-HER2 antibody.

31. (currently amended): The method of claim 28, wherein said anti-HER2 antibody is a humanized or chimeric form of a murine antibody selected from the group consisting of 4D5 (ATCC Number CRL-10463) and 520C9 (ATCC Number HB-8696).

32. (currently amended): The method of claim 16, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is in the range from about 2.0 mg/kg to

about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.6 MIU/m^2 to about 3.0 MIU/m^2.

33. (currently amended): The method of claim 32, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.8 MIU/m^2 to about 1.5 MIU/m^2.

34. (currently amended): The method of claim 33, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is about 4.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is about 1.0 MIU/m^2.

35. (currently amended): The method of claim 17, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.6 MIU/m^2 to about 3.0 MIU/m^2.

36. (currently amended): The method of claim 35, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.8 MIU/m^2 to about 1.5 MIU/m^2.

37. (currently amended): The method of claim 36, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is about 4.0 mg/m^2 and wherein said therapeutically effective dose of said IL-2 or variant thereof is about 1.0 MIU/m^2.

38. (currently amended): The method of claim 18, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.6 MIU/m^2 to about 3.0 MIU/m^2.

39. (currently amended): The method of claim 38, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.8 MIU/m^2 to about 1.5 MIU/m^2.

40. (currently amended): The method of claim 39, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is about 4.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is about 1.0 MIU/m^2.

41. (previously presented): The method of claim 19, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle and on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of said IL-2 or variant thereof, wherein said intermediate dose is about 12.0 MIU/m^2.

42. (currently amended): A method of treating a subject for a breast cancer characterized by overexpression of the HER2 receptor protein, said method comprising concurrent therapy with an anti-HER2 antibody ~~or fragment thereof~~ that has anti-tumor activity and an interleukin-2 (IL-2) polypeptide comprising the sequence of SEQ ID NO:1 or biologically active variant thereof, wherein said anti-HER2 antibody ~~or fragment thereof binds the same epitope as~~ comprises a complementarity determining region (CDR) of an anti-HER2 antibody selected from the group consisting of 4D5 (ATCC Number CRL-10463) and 520C9 (ATCC Number HB-8696), wherein said anti-HER2 antibody binds to the extracellular domain of the HER2 receptor protein, wherein said concurrent therapy comprises daily administration of a therapeutically effective dose of said IL-2 or variant thereof on day 1 of an introductory cycle through day 20 of said introductory cycle, and a single administration of a therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ on day 7 of said introductory cycle; wherein said variant of said IL-2 has anti-tumor activity and ~~comprises an amino acid sequence having~~ at least 90% sequence identity to SEQ ID NO:1 as calculated using the ALIGN program with a PAM 120

weight residue table, a gap length penalty of 12, and a gap penalty of 4, and wherein said anti-HER2 antibody ~~or fragment thereof~~ binds to the extracellular domain of the HER2 receptor protein.

43. (currently amended): The method of claim 42, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or biologically active variant thereof is in the range from about 0.5 MIU/m^2 to about 4.0 MIU/m^2.

44. (currently amended): The method of claim 43, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is in the range from about 2.0 mg/kg to about 9.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.6 MIU/m^2 to about 3.0 MIU/m^2.

45. (currently amended): The method of claim 44, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is in the range from about 3.0 mg/kg to about 8.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is in the range from about 0.8 MIU/m^2 to about 1.5 MIU/m^2.

46. (currently amended): The method of claim 45, wherein said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ is about 4.0 mg/kg and wherein said therapeutically effective dose of said IL-2 or variant thereof is about 1.0 MIU/m^2.

47. (currently amended): The method of claim 42, further comprising administering said therapeutically effective dose of said IL-2 or variant thereof and said therapeutically effective dose of said anti-HER2 antibody ~~or fragment thereof~~ during at least one subsequent cycle, wherein said subsequent cycle comprises daily administration of said therapeutically effective dose of said IL-2 or variant thereof on day 1 of said subsequent cycle through day 14 of said subsequent cycle, and administration of said therapeutically effective dose of said anti-HER2 antibody on day 1 of said subsequent cycle.

48. (previously presented): The method of claim 42, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of said IL-2 or variant thereof, wherein said intermediate dose is about 12.0 MIU/m^2.

49. (previously presented): The method of claim 47, further comprising intermediate-dose IL-2 pulsing on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of said IL-2 or variant thereof, wherein said intermediate dose is about 12.0 MIU/m^2.

50. (previously presented): The method of claim 47, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle and on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 or variant thereof an intermediate dose of said IL-2 or variant thereof, wherein said intermediate dose is about 12.0 MIU/m^2.

51. (canceled)

52. (currently amended): The method of claim 12, wherein said anti-HER2 antibody is a humanized form of a murine antibody selected from the group consisting of 4D5 (ATCC Number CRL-10463) and 520C9 (ATCC Number HB-8696).

53. (previously presented): The method of claim 52, wherein said IL-2 or variant thereof is recombinantly produced.

54. (canceled)

55. (currently amended): The method of claim 16, wherein said anti-HER2 antibody is a humanized form of a murine antibody selected from the group consisting of 4D5 (ATCC Number CRL-10463) and 520C9 (ATCC Number HB-8696).

56. (previously presented): The method of claim 55, wherein said IL-2 or variant thereof is recombinantly produced.

57. (canceled)

58. (currently amended): The method of claim 17, wherein said anti-HER2 antibody is a humanized form of a murine antibody selected from the group consisting of 4D5 (ATCC Number CRL-10463) and 520C9 (ATCC Number HB-8696).

59. (previously presented): The method of claim 58, wherein said IL-2 or variant thereof is recombinantly produced.

60. (canceled)

61. (currently amended): The method of claim 42, wherein said anti-HER2 antibody is a humanized form of a murine antibody selected from the group consisting of 4D5 (ATCC Number CRL-10463) and 520C9 (ATCC Number HB-8696).

62. (previously presented): The method of claim 61, wherein said IL-2 or variant thereof is recombinantly produced.

63. (currently amended): A method of treating a subject for a breast cancer characterized by overexpression of the HER2 receptor protein, said method comprising concurrent therapy with an IL-2 polypeptide comprising the amino acid sequence of SEQ ID NO:1 and a humanized anti-HER2 antibody selected from the group consisting of a humanized 4D5 antibody (ATCC Number CRL-10463) and a humanized 520C9 antibody (ATCC Number HB-8696), wherein said

concurrent therapy comprises administering to said subject at least one therapeutically effective dose of said IL-2 polypeptide in combination with a dosing regimen for said humanized anti-HER2 antibody, wherein said dosing regimen for said humanized anti-HER2 antibody comprises administering to said subject at least one therapeutically effective dose of said humanized anti-HER2 antibody, wherein said therapeutically effective dose of said humanized anti-HER2 antibody is in the range from about 1.0 mg/kg to about 10.0 mg/kg and wherein said therapeutically effective dose of said IL-2 polypeptide is in the range from about 0.5 MIU/m^2 to about 4.0 MIU/m^2.

64. (currently amended): The method of claim 63, wherein said anti-HER2 antibody is a humanized 4D5 (ATCC Number CRL-10463) antibody.

65. (currently amended): The method of claim 63, wherein said anti-HER2 antibody is a humanized 520C9 (ATCC Number HB-8696) antibody.

66. (previously presented): The method of claim 63, wherein said therapeutically effective dose of said humanized anti-HER2 antibody is about 4.0 mg/kg and wherein said therapeutically effective dose of said IL-2 polypeptide is about 1.0 MIU/m^2.

67. (currently amended): The method of claim 63, wherein said concurrent therapy comprises a first administration of a therapeutically effective dose of said IL-2 polypeptide on day 1 of a treatment period followed by a first administration of a therapeutically effective dose of said humanized anti-HER2 antibody ~~or fragment thereof~~ within 6 days of said first administration of said therapeutically effective dose of said IL-2 polypeptide to said subject.

68. (previously presented): The method of claim 63, wherein said concurrent therapy comprises multiple dosing of a therapeutically effective dose of said humanized anti-HER2 antibody and a therapeutically effective dose of said IL-2 polypeptide.

69. (previously presented): The method of claim 68, wherein said multiple dosing comprises administering to said subject said therapeutically effective dose of IL-2 polypeptide and said therapeutically effective dose of said humanized anti-HER2 antibody during an introductory cycle, wherein said introductory cycle comprises daily administration of said therapeutically effective dose of said IL-2 polypeptide on day 1 of said introductory cycle through day 20 of said introductory cycle, and a single administration of said therapeutically effective dose of said humanized anti-HER2 antibody on day 7 of said introductory cycle.

70. (previously presented): The method of claim 63, further comprising administering said therapeutically effective dose of said IL-2 polypeptide and said therapeutically effective dose of said humanized anti-HER2 antibody during at least one subsequent cycle, wherein said subsequent cycle comprises daily administration of said therapeutically effective dose of said IL-2 polypeptide on day 1 of said subsequent cycle through day 14 of said subsequent cycle, and administration of said therapeutically effective dose of said humanized anti-HER2 antibody on day 1 of said subsequent cycle.

71. (previously presented): The method of claim 69, further comprising intermediate-dose IL-2 pulsing on days 8-10 of said introductory cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 polypeptide an intermediate dose of said IL-2 polypeptide, wherein said intermediate dose is about 12.0 MIU/m^2.

72. (previously presented): The method of claim 70, further comprising intermediate-dose IL-2 pulsing on days 1-3 of said subsequent cycle, wherein said pulsing comprises administering in place of said therapeutically effective dose of said IL-2 polypeptide an intermediate dose of said IL-2 polypeptide, wherein said intermediate dose is about 12.0 MIU/m^2.

73. (previously presented): The method of claim 63, wherein said IL-2 polypeptide is administered subcutaneously.

74. (currently amended): The method of claim 31, wherein said anti-HER2 antibody is Herceptin® recombinant humanized 4D5 monoclonal antibody.

75. (currently amended): The method of claim 52, wherein said anti-HER2 antibody is Herceptin® recombinant humanized 4D5 monoclonal antibody.

76. (currently amended): The method of claim 55, wherein said anti-HER2 antibody is Herceptin® recombinant humanized 4D5 monoclonal antibody.

77. (currently amended): The method of claim 58, wherein said anti-HER2 antibody is Herceptin® recombinant humanized 4D5 monoclonal antibody.

78. (currently amended): The method of claim 61, wherein said anti-HER2 antibody is Herceptin® recombinant humanized 4D5 monoclonal antibody.

79. (currently amended): The method of claim 63, wherein said anti-HER2 antibody is Herceptin® recombinant humanized 4D5 monoclonal antibody.